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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,787	07/28/2003	Slobodan Dan Dimitrijevich	UNTF:1003RCE	5209

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EXAMINER	
GHALI, ISIS A D	
ART UNIT	PAPER NUMBER
1611	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/628,787	DIMITRIJEVICH, SLOBODAN DAN	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *41-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *41-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' request for RCE filed 12/31/2007, and amendment filed 01/23/2008.

Claims 1-40 have been canceled.

Claims 41-60 are pending and included in the prosecution.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/31/2007 has been entered.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 41-60 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,599,526 ('526). Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are directed to anti-adhesion patch made by a process comprising the steps of mixing human connective tissue cells with collagen wherein the cell organize the collagen into patch. The claims of the issued patent '526 are directed to method of making anti-adhesion patch comprising the steps of mixing human connective tissue cells with collagen wherein the cell organize the collagen into patch. Therefore, the issued claims anticipate the present claims.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 41-60 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 41-60 as amended introduced new matter that is not supported by the specification as originally filed. The recitation of "molecular collagen" in claims 41 and 51 introduced new matter that is not supported by the original specification. Claim 51 further recites "cell culture conditions" and "for 14 days or less", no support to such limitations is found in the specification.

In accordance to MPEP 714.02, applicant should specifically point out to where in the disclosure a support for any amendment made to the claims can be found.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 41-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 51 recites the expression "cell culture conditions" that does not set forth the metes and bounds of the claims. Recourse to the specification does not define the expression in terms of what are the cell culture conditions.

Claims 41-60 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted element is: collaged type I as element of the mixed elements. Claims 41 and 51 are directed to product by process, and recite one step of “mixing a human fibroblast cells” and do not recite any other components to be mixed with the human fibroblast cells. The claims further recite the function of the fibroblast cells to adapt and organize the Type I collagen molecules. Collagen Type I is not recited as element to be mixed with human fibroblast cells to form the claimed product.

Claims 41 and 51 recite the limitation "the Type I collagen" in the second and forth lines of each claim. There is insufficient antecedent basis for this limitation in claims 41 and 51.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 41-44, 46, 47, 49-54, 56, 57, 59-60 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,700,688 (‘688).

> The present claims are directed to patch comprising human fibroblast cells and collagen Type I. The capability of the patch to act as anti-adhesive is inherent for the patch comprising the claimed

elements, as well as the capability of fibroblast to organize collagen is inherent function of the fibroblast.

US '688 disclosed tissue equivalent material formed in vitro from collagen type I and III mixed with human fibroblast (col.4, lines 25-30, 48-60; col.5, lines 20-25; col.10, lines 28-33). The mixture is incubated under standard cell culture conditions wherein the cells organize collagen fibrils to form gel material (col.5, lines 33-37). The reference disclosed incubation for 7 days (col.19, lines 18-21), meeting the limitation of claim 51 of less than 14 days. The reference teaches washing, centrifuging and filtering the mixture (col.11, lines 12-33), and this implied removal of the cells from the composition as required by claims 47 and 57. The mixture further comprises TGFB (col.10, lines 14-15). Inherently, the provided tissue equivalent material will have anti-adhesion properties and will be adapted for use in different body cavities and during cardiac surgery. The claims are directed to product, and the method of making the product does not impart patentability to the claims, and patentability is determined by the product produced. All the elements of the product are disclosed by the reference, therefore it is capable to perform the anti-adhesion function, and hence, the reference anticipates the present claims. The capability of the patch to act as anti-adhesive is inherent for the patch comprising the claimed elements, as well as the capability of fibroblast to organize collagen is inherent function of the fibroblast. The step of removing the cells from the patch as claimed by claims 47 and 57 is directed to the method of making the patch that does not impart patentability to claims directed to product.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 45 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over US ‘688 in view of US 6,077,978 (‘987).

The teachings of US ‘688 are discussed in section 9 as set forth in this office action.

However, US '688 does not teach the fibroblast cells to be engineered cells as claimed by claims 45 and 55.

US '987 teaches method for enhancing the efficacy of tissue repair and promoting wound healing using engineered cells in a protein matrix (abstract; co1.4, lines 5-13). The engineered cells are fibroblast from epidermal cells (col.4, lines 35-38, 45-50).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide tissue equivalent material formed from mixture of collagen type I and human fibroblast as disclosed by US '688, and replace fibroblast by engineered dermal fibroblast as disclosed by US '987, motivated by the teaching of US '987 that the engineered cells enhance the efficacy of tissue repair and promote wound healing, with reasonable expectation of having tissue equivalent material comprising collagen type I and engineered fibroblast that enhances the efficacy of tissue repair and promotes wound healing without causing adhesion between the adjacent tissues, as desired by applicants.

13. Claims 47 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over US ‘688 in view of US 5,899,936 (‘936).

The teachings of US ‘688 are discussed in section 9 as set forth in this office action.

However, US '688 does not teach step of removing the cells from the patch as claimed by claims 47 and 57.

US ‘936 teaches method of generating implant from collagens including the step of removing cells from collagens to kill the native cells and remove potentially

immunologically active soluble molecules because viable cells may elicit adverse immune response (abstract; col. 4, lines 25-29).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide tissue equivalent material formed from mixture of collagen type I and human fibroblast as disclosed by US '688, and further remove the viable cells from the tissue equivalent as disclosed by US '936 because US '936 teaches that viable cells may elicit adverse immune response and their removal will remove potentially immunologically active soluble molecules, with reasonable expectation of having tissue equivalent material comprising collagen type I and engineered fibroblast from which viable cells are removed with no adverse immune effect upon use.

14. Claims 48 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '688 in view of US 5,580,923 ('923).

The teachings of US '688 are discussed in section 9 as set forth in this office action.

However, US '688 does not teach fibrin glue disposed on the patch as claimed by claims 48 and 58.

US '923 teaches anti-adhesion film useful to prevent surgical adhesion and comprising collagen substrate that is attached to the tissue using biomedical adhesive with the most preferred method of attachment involves taping using fibrin glue to avoid suturing (abstract; col.13, lines 43-56).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide tissue equivalent material formed from mixture of collagen type I and human fibroblast as disclosed by US '688, and further attach the tissue equivalent to the tissues using taping by fibrin as disclosed by US '923 because US '923 teaches that the most preferred method of attaching anti-adhesion patch to the tissue is by taping using fibrin glue to avoid suturing, with reasonable expectation of having tissue equivalent material comprising collagen type I and engineered fibroblast and further comprising fibrin glue deposited on it to safely and effectively attach the film to the tissue without further damage caused by suturing.

Response to Arguments

15. Applicant's arguments filed 01/123/2008 have been fully considered but they are not persuasive. The main gist of applicants' argument against the anticipatory rejection over US '688 is that the reference teaches cross linked oriented collagen tissue equivalent seeded with viable cells, while the present patch is non-oriented and not seeded with fibroblast.

In response to the above arguments that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., cross linked oriented collagen tissue equivalent seeded with viable cells) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The present claims are

directed to product, and all the elements of the claims, i.e. collagen and fibroblasts, are disclosed by US '688, and the claims are anticipated. The capability of the patch to act as anti-adhesive is inherent for the patch comprising the claimed elements, as well as the capability of fibroblast to organize collagen is inherent function of the fibroblast. Seeding or mixing the fibroblast into the collagen, is directed to method of making the patch that does not impart patentability to claims directed to product. Product by process claims are not limited to the manipulation of the recited steps, only the structure implied by the steps. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by- process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695, 698,227 USPQ 964,966 (Fed. Cir.1985). The structure implied by the process steps should be considered when assessing the patentability of product- by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Gamero*, 412 F.2d 276,279, 162 USPQ 221,223 (CCPA 1979). "The Patent Office bears a lesser burden of proof in making out a case of prima facie obviousness for product-by-process claims because of their peculiar nature" than when a product is claimed in the conventional fashion. In re *Fessmann,* 489 F.2d 742, 744, 180 USPQ 324,326 (CCPA 1974); *In re Marosi*, 710

F.2d 798,802,218 USPQ 289, 292 (Fed. Cir.1983). Since the present composition is substantially identical to the composition disclosed by US '688, the burden is on appellants to show an unobvious difference of the claimed product over the prior art.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

IG

/Isis A Ghali/
Primary Examiner, Art Unit 1611